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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,826	11/22/1999	RODERICK J. CHAPPEL	DAVIE79.001A	3117

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/20/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,826	CHAPPEL	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20,75,124-126 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,75 and 124-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Amendment Entry

1. The examiner acknowledges the amendment filed October 4, 2001. Claims 1-13, 15-17, 19-20 and 124-126 have been amended. Claims 21-74 and 76-123 have been canceled. Therefore, claims 1-20, 75 and 124-126 are pending and under consideration in this office action.

Withdrawal of Rejections

2. In view of applicant's remarks and the amendments, the following objections and rejections are being withdrawn:

a) the objection of claim 12 for containing informalities;

b) the rejection of claims 2, 19 and 20 under 35 U.S.C. 112, first paragraph

c) the rejection of claims 1-20, 75 and 124-126 under 35 U.S.C. 112, second paragraph,

d) the rejection of claims 1-2 and 15-18 under 35 U.S.C. 102(a) as being anticipated by Perolat et al., (EMBL U60594)

Response to Arguments

3. Applicant's arguments filed December 13, 20001 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1-2 and 15-18 under 35 U.S.C. 102(b) as being anticipated by Hookey (EMBL Z21634) is maintained. The rejection was on the grounds that the entry in the EMBL database described [redacted] a phylogeny of *Leptospira* and related spirochetes. The source of the organism is from *Leptospira inadai* and the strain Lyme, wherein the product is a 16S ribosomal RNA sequence. This sequence is 1374 base pairs long. Therefore this entry teaches an isolated pathogenic Leptospira bacterium [redacted] which is serologically cross-reactive to the deposited strain.

Applicant urges that Dr. Chappel declares that there is no serological cross-reactivity between *L. inadai* and the deposited strain; thus the claims are clearly novel over the Hookey disclosure. However, it is the examiner's position that both the declaration and the arguments presented merely state a conclusion without providing any determinative scientific data. There is no side-by-side comparison showing a lack of cross-reactivity using the MAT test or any test for cross-reactivity as disclosed by the specification. The arguments and specification merely provide speculation that there would be no cross-reactivity without scientific proof. The fact that the disclosure does not specifically state that the strain is cross-reactive with the deposited strain is not persuasive. Applicant must show conclusive evidence that the strain is not cross-reactive, without such a showing the rejection will be maintained.

5. The rejection of claims 1-6, 10 and 19 under 35 U.S.C. 102(b) as being anticipated by Perolat et al., (Abstracts). The rejection was on the grounds that Perolat et al., teach molecular and phenotypic characterization of Hurstbridge strains as a new genomic species of pathogenic *Leptospira*.

It is applicant's position that it is not possible to determine that the isolate by Perolat et al., ~~are~~ is serologically cross-reactive to the deposited strain. Applicant states that the genetic relationship is not predicative of serological cross-reactivity, thus the rejection should be withdrawn. However, the examiner urges that the declaration and the arguments state a conclusion without providing any determinative scientific evidence. There ~~is~~ are no data showing a lack of cross-reactivity using the test for cross-reactivity as taught by the specification. The arguments and specification simply provide speculation about cross-reactivity without any scientific proof. The fact that the authors did not comptemplate the strains cross-reactivity with the deposited strain is irrelevant. The issue is whether there is or is not cross-reactivity. Applicant has not provided data that would enable a person skilled in the art to determine whether or not there is cross-reactivity. Applicant must show conclusive evidence that the strain is not cross-reactive, without such a showing the rejection will be maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of

Chappel et al., (Manipulating Pig Production) is maintained. The rejection was on the grounds that it would have been obvious at the time of applicant's invention to have incorporated known information about human infection by *Leptospira* bacterium as taught by Chappel et al., (Manipulating Pig Production) and apply it to the known *Leptospira* bacteria as taught by Hookey (EMBL Z21634) or Perolat et al., (Abstracts), because Chappel et al., (Manipulating Pig Production) teach that human *Leptospira* infection is an important field of research.

Applicant urges that neither Hookey (EMBL Z21634) nor Perolat et al., (Abstracts) teach or suggest the deposited strain or the strains that are cross-reactive with the deposited strain, thus there would have been no motivation to combine the references.

The rejected claims are not drawn to the deposited strain, but rather to a strain that is cross-reactive. Since applicants have been presented evidence to the contrary, the strain of the prior art will be presumed to be cross-reactive. See also the previous discussion.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than

routine skill would have been required to have used well known information about human infection by *Leptospira* bacterium as taught by Chappel et al., (Manipulating Pig Production) and apply it to the *Leptospira* bacteria as taught by Hookey (EMBL Z21634) or Perolat et al., (Abstracts), because Chappel et al., (Manipulating Pig Production) teach pathogenic strains of *Leptospirosis* are known to affect pigs reproductive performance, while human leptospirosis of pig origin is an important zoonosis; also research showed evidence of a new previously unrecognized serovar of *Leptospira* wherein human *Leptospira* infection is an important field of research.

7. The rejection of claims 8, 11-14 under 35 U.S.C. 103(a) as being unpatentable over Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of Chappel et al., (Pig Research Report) is maintained. Hookey (EMBL Z21634) and Perolat et al., (Abstracts) have been discussed above.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, Chappel et al., (Pig Research Report) teach that infection of *Leptospira* can cause infertility, abortions, early embryonic loss, stillbirths, and is associated with seasonal infertility. The authors research points to a previously

undiscovered leptospiral serovar that are members of the pathogenic species *Leptospira inadai* and a serovar within the *L.inadai.*

Accordingly, no more than routine skill would have been required to used the known infection capabilities of *Leptospira* as taught by Chappel et al., (Pig Research Report) with the isolated *Leptospira* bacterium of Hookey (EMBL Z21634) or Perolat et al., (Abstracts) because Chappel et al., (Pig Research Report) teach that reproductive problems are well known to be associated with *Leptospira* infections in pigs and bovines.

8. The rejection of claims 5-8, 10, 12, 75 and 124-126 under 35 U.S.C. 103(a) as being unpatentable over Hookey (EMBL Z21634) or Perolat et al., (Abstracts) in view of Haake et al., (US Patent 6,643,754) is maintained. Hookey (EMBL Z21634) and Perolat et al., (Abstracts) have been discussed above. Again, in light of the fact that there is no evidence of record showing that the strains are not cross-reactive, it will be presumed that the strains are cross-reactive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have

been obvious at the time of applicants invention to combine Leptospira with a pharmaceutically acceptable diluent as taught by Haake et al., with the bacterium of Hookey (EMBL Z21634) or Perolat et al., (Abstracts) because Haake et al., state that such compositions may induce an immune response in animals.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703) 308-0196.

Ja-Na Hines

December 13, 2001

LYNETTE R. F. SMITH
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